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Variability of the pullout strength of cancellous bone screws with cement augmentation

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ABSTRACT

Background: Orthopaedic surgeons often face clinical situations where improved screw holding power in cancellous bone is needed. Injectable calcium phosphate cements are one option to enhance fixation.
Methods: Paired screw pullout tests were undertaken in which human cadaver bone was augmented with calcium phosphate cement. A finite element model was used to investigate sensitivity to screw positional placement.
Findings: Statistical analysis of the data concluded that the pullout strength was generally increased by cement augmentation in the in vitro human cadaver tests. However, when comparing the individual paired samples there were surprising results with lower strength than anticipated after augmentation, in apparent contradiction to the generally expected conclusion. Investigation using the finite element model showed that these strength reductions could be accounted for by small screw positional changes. A change of 0.5 mm might result in predicted pullout force changes of up to 28%.
Interpretation: Small changes in screw position might lead to significant changes in pullout strength sufficient to explain the lower than expected individual pullout values in augmented cancellous bone. Consequently whilst the addition of cement at a position of low strength would increase the pullout strength at that point, it might not reach the pullout strength of the un-augmented paired test site. However, the overall effect of cement augmentation produces a significant improvement at whatever point in the bone the screw is placed. The use of polymeric bone-substitute materials for tests may not reveal the natural variation encountered in tests using real bone structures.

1. Introduction

Many orthopaedic surgeons report difficulties of fixing bone screws (e.g. Andersson et al., 2000 or Strømsøe, 2004), especially into poor quality cancellous bone of low apparent density—bone with low bone volume to total volume (BV/TV) ratios. Bone quality and quantity in patients presenting with fragility fractures are often variable (e.g. Berlemann and Schwarzenbach, 1997; Chen et al., 2009; Thiele et al., 2007), and control of screw fixation in a surgical situation is challenging.

The number of clinically reported screw failures is high especially in patients with poor bone quality. Hip fracture screw failure rates vary between 3% and 5% (Jesudason and Jeyem, 2006; Kim et al., 2001) while for proximal humeral fractures rates can vary between 15% and 40% (Singer et al., 1998; Cantlon and Egol, 2013). It has been suggested (Procter, 2013) that the total number of screw failures due to loosening and/or migration worldwide is at least one million annually, and while some failures will not have significant clinical consequences, some may need immediate and costly surgical revision. To overcome some of these difficulties, the use of cement for screw augmentation is often considered. The clinical evidence for cement augmentation is presented in a recent meta-analysis by Namdari et al. (2013). They concluded that "Augmentation of intertrochanteric femur fractures with polymethyl methacrylate or calcium–phosphate may provide benefits in terms of radiographic parameters and complication rates".

Screw pullout strength is often predicted using pullout tests from bone models such as Sawbones™ (Ramaswamy et al., 2010; Flahiff et al., 1995; Yánez et al., 2010; Augat et al., 2002; Brown et al., 2000; Schoenfeld et al., 2008; Patel et al., 2010), and tests reported by Asnis et al. (1996) suggest that good agreement is reached in porous foams of various densities. However Chapman et al. (1996) found the strength range for the tests in a homogenous Sawbones™ material and those data available for human bone differ considerably. Tests of screw pullout with cement augmentation are therefore even more difficult, as bone-substitute materials with appropriate mechanical strength and stiffness

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properties are often porous but with closed pores (as recommended by ASTM F543-07e1, 2007), meaning that cement distribution is limited and unrealistic, and in consequence the increase in measured pullout strengths can be unrealistically low. There are grades of Sawbones™ with interconnected porosity. However the cement distribution is unrealistically large and measured pullout forces will be overstated. The use of real bone may therefore be preferred (Andreassen et al., 2004; Collinge et al., 2007; Eriksson et al., 2002; Hoshikawa et al., 2003; Larsson and Procter, 2011; Leung et al., 2006; Mader et al., 2003; McKoy and An, 2000; Renner et al., 2004; Verlaan et al., 2006), but the fundamental structure can lead to significant variability (Bayraktar et al., 2004; Keaveny et al., 1994; Rincon Kohli, 2003), particularly when it involves poor quality osteopenic or osteoporotic bone. Repeatability of results can be difficult. Seebeck et al. (2005) have shown that this variability exists in pullout of screws from human bone. The evaluation of fixation devices through testing in poor quality bone, either human or animal, therefore often requires a large number of specimens to achieve significance.

Orthopaedic practitioners have used injectable cement in a predrilled screw hole, back-filled with cement prior to screw insertion to increase pullout strength and improve "stability". It is generally regarded as beneficial in its use with both cancellous and cortical screws (Gefen, 2002; Gausepohl et al., 2001). Particularly, Larsson et al. (2012) have shown that bone augmentation using calcium phosphate cements in a lapine in vivo model gives significantly improved pullout strength. As a result it might be expected that augmentation with cement should always improve fixation, and consequently improve surgical outcome.

As additional evidence of augmented screw performance through the use of a particular calcium phosphate cement (Hydroset®) in human bone, a series of human cadaver tests was carried out using ten paired femurs, correcting for local density as determined through CT scans. However, in the analysis of the results of pullout force normalised for density from these tests on human bone it became evident that a small number of anomalous results were present. Because of the unexpected results a further series of ten human cadaver tests, was undertaken. These again showed similar anomalous results.

This pullout strength data from tests using bone screws inserted into calcium phosphate cement in human femurs is presented below. Our hypothesis is that these variations could occur as a result of small changes of screw insertion position, and finite element models provide data on the consequent variability of pull out strength. The discussion demonstrates how this might explain the unexpected test data obtained.

2. Methods

Two methods are presented. First, the methodology for the human cadaver study is detailed. Secondly, a brief outline of a simplified finite element model used to demonstrate relative values of screw pullout is presented; fuller descriptions and validation methods are given elsewhere (Brown et al., 2013).

2.1. Human cadaver study

The distal parts of eleven human femurs (numbers 1 to 11) were dissected from cadavers that were previously fixed in a solution of 91% alcohol, 2% formaldehyde and 7% phenol, and were kept in a refrigerator at approximately 4 °C. No precise identification of the bones was available but they were thought to be mostly from middle-aged donors who did not suffer from diseases such as osteoporosis or arthritis.

Two cylinders of 25 mm diameter and about 20 mm length were extracted from the condyle of each femur. A hollow mill placed on a power drill running at 400 r.p.m. was used to cut out the cylinders. The specimens were then separated from the bone with a manual saw. The specimens were taken on the anterior–lateral and on the anterior–medial side of the condyles and then put in hermetically closed tubes (standard laboratory Falcon tubes), identified by the sample references (ID) and then again stored in the refrigerator at approximately 4 °C.

The accuracy of the bone mineral density measurements (BMD) made using a CT scanner (Densiscan1000, QCT, Scanco, Brüttisellen, Switzerland) was checked with a reference "phantom". The specimens were placed in the scanner within the Falcon tube. A special fixture made of polystyrene foam and a metal point was used to align the surface of the sample (cortical side) with the scan starting plan and to align the axis of the sample with the axis of the scanner. Seven slices, starting from the bone surface in the direction of the bone core, were scanned each 2 mm. The mean density was then calculated in circles of about 6 mm diameter on the slices where the metal point was no longer visible. This procedure ensured a density measurement of the exact bone volume in which the screw was to be placed. The Falcon tubes containing the samples were then put back to the refrigerator at 4 °C.

To place the screws and cement, the Falcon tube containing the specimens was plunged for about 1 h in a water container heated to 37 °C (Fig. 1). The samples, which had reached the body temperature after that time, were then placed in a purpose-made fixture box (Fig. 1) and a hole of 2.5 mm diameter was drilled 10 mm deep at the same location and along the axis of the bone cylinder that had been scanned. The hole was then tapped 10 mm deep with the correct manufacturer-recommended tap for 4.0 mm screws. Finally, the specimens were placed back in the Falcon tubes and plunged in the 37 °C bath.

The calcium phosphate cement (Hydroset®, Stryker) packs were stored for about 1 h in the room where the bone augmentation procedure took place. The room temperature was set at 19 °C. The bone/screw samples, kept in the Falcon tubes, were taken out from the 37 °C warm bath just before augmentation. The Hydroset liquid was mixed with the powder for 45 s. At 2 min, the mixture was injected in the pre-drilled holes and at 3 min the screws (standard orthopaedic screws 4 mm diameter × 35 mm long) were inserted 10 mm deep. After that the specimens were again placed in the special fixture box and back into the Falcon tubes immediately after screwing, and then plunged in the 37 °C bath for 4 h. The specimen selection process for augmented or non-augmented was randomised. Where the bone sample of the pair was not augmented, the same procedure for screw placement and temperature control was followed—with the omission of cement injection. One randomly selected sample (numbered 2) was

Fig. 1. Falcon tube and specimen.